UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION **MDL No. 2326**

THIS DOCUMENT RELATES TO THE FOLLOWING CASES:

ADAMS, Ida vs. BOSTON SCIENTIFIC CORP., 17-cv-02588
ALLEN, Kimberly vs. BOSTON SCIENTIFIC CORP., 17-cv-01837
ALLEX, Dominique vs. BOSTON SCIENTIFIC CORP., 17-cv-02443
ALVARADO, Perla vs. BOSTON SCIENTIFIC CORP., 17-cv-02243
ATWOOD, Jennifer vs. BOSTON SCIENTIFIC CORP., 17-cv-02202
BABCOCK, Christine vs. BOSTON SCIENTIFIC CORP., 17-cv-00701
BARNETT, Cheryl vs. BOSTON SCIENTIFIC CORP., 17-cv-02589
BENSON, Angela vs. BOSTON SCIENTIFIC CORP., 17-cv-01996
BLACK, Roberta vs. BOSTON SCIENTIFIC CORP., 17-cv-02730
BLALOCK, Laceta vs. BOSTON SCIENTIFIC CORP., 17-cv-02446
BROWN, Tracy vs. BOSTON SCIENTIFIC CORP., 17-cv-01243
BUSBY, Amy vs. BOSTON SCIENTIFIC CORP., 17-cv-02111
BUTTKE, Louise vs. BOSTON SCIENTIFIC CORP., 17-cv-02638
CASALE, Claire vs. BOSTON SCIENTIFIC CORP., 17-cv-02447
CHILDRESS, Carolyn, vs. BOSTON SCIENTIFIC CORP., 17-cv-02590
CLARK, June vs. BOSTON SCIENTIFIC CORP., 17-cv-02448
CLARK, Sandra vs. BOSTON SCIENTIFIC CORP., 17-cv-02110
COLE, Bonnie vs. BOSTON SCIENTIFIC CORP., 17-cv-02449
CONLEY, Jaime vs. BOSTON SCIENTIFIC CORP., 17-cv-01940
CUTLIP, Lisa G. vs. BOSTON SCIENTIFIC CORP., 17-cv-02505
DANIELL, Edwina vs. BOSTON SCIENTIFIC CORP., 17-cv-02486
DEMBSKI, Linda vs. BOSTON SCIENTIFIC CORP., 17-cv-01074
DICKESON, Penny vs. BOSTON SCIENTIFIC CORP., 17-cv-02592
DUNFORD, Glenda and Delbert Dunford vs. BOSTON SCIENTIFIC CORP., 17-cv-01979
EVANS, Bonnie vs. BOSTON SCIENTIFIC CORP., 17-cv-01242
FASO, Susan and Carmen Faso vs. BOSTON SCIENTIFIC CORP., 17-cv-01862
GOTTFREID, Debra vs. BOSTON SCIENTIFIC CORP., 17-cv-02646
GRIGG, Teresa R. vs. BOSTON SCIENTIFIC CORP., 17-cv-00294
HARDWICK, Zena vs. BOSTON SCIENTIFIC CORP., 17-cv-01977
HARRISON-HOOD, Amy vs. BOSTON SCIENTIFIC CORP., 17-cv-02641
HAUFF, Anita Lynne and Frederick J. Hauff vs. BOSTON SCIENTIFIC CORP., 17-cv-01900
HENJUM, Linda vs. BOSTON SCIENTIFIC CORP., 17-cv-02734
JETER, Marsha Sue vs. BOSTON SCIENTIFIC CORP., 17-cv-02508
LONG, Shelia vs. BOSTON SCIENTIFIC CORP., 17-cv-00047
LOPEZ, Deann vs. BOSTON SCIENTIFIC CORP., 17-cv-01155
LOWRIE, Tracy vs. BOSTON SCIENTIFIC CORP., 17-cv-01959
MAHNKE, Dana vs. BOSTON SCIENTIFIC CORP., 17-cv-00568

MALLORY, Sandra vs. BOSTON SCIENTIFIC CORP., 17-cv-02459
MARTIN, Delores Jackson vs. BOSTON SCIENTIFIC CORP., 17-cv-02738
MARTIN, Joyce vs. BOSTON SCIENTIFIC CORP., 17-cv-02461
MARTINEZ, Dolores vs. BOSTON SCIENTIFIC CORP., 17-cv-02739
MASTERSON, Mary vs. BOSTON SCIENTIFIC CORP., 17-cv-02417
MCFOLLING, Marlene vs. BOSTON SCIENTIFIC CORP., 17-cv-02596
MCSWEEN, Belinda vs. BOSTON SCIENTIFIC CORP., 17-cv-02462
MELROSE, Mary vs. BOSTON SCIENTIFIC CORP., 17-cv-02467
MORALES, Geraldine vs. BOSTON SCIENTIFIC CORP., 17-cv-02742
MORGAN, Flora vs. BOSTON SCIENTIFIC CORP., 17-cv-02597
MURRAY, Beverly Ingrid Pamensky vs. BOSTON SCIENTIFIC CORP., 17-cv-02093
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PORTER, Annie vs. BOSTON SCIENTIFIC CORP., 17-cv-02470
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PRICE, Armentha vs. BOSTON SCIENTIFIC CORP., 17-cv-01939
REID, Nancy vs. BOSTON SCIENTIFIC CORP., 17-cv-02598
REYES, Lori vs. BOSTON SCIENTIFIC CORP., 17-cv-02599
RINALDI, Ellen vs. BOSTON SCIENTIFIC CORP., 17-cv-02600
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SCHRODER, Annette vs. BOSTON SCIENTIFIC CORP., 17-cv-01938
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SHEPARD, Anne Marie vs. BOSTON SCIENTIFIC CORP., 17-cv-02481
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SMITH, Judy vs. BOSTON SCIENTIFIC CORP., 17-cv-02483
SOLOMON, Pamela vs. BOSTON SCIENTIFIC CORP., 17-cv-02551
SPEED, Margaret vs. BOSTON SCIENTIFIC CORP., 17-cv-02244
SPENCER, Yvonne vs. BOSTON SCIENTIFIC CORP., 17-cv-02553
STAPF, Bonnie vs. BOSTON SCIENTIFIC CORP., 17-cv-02787
SUSTAITA, Stella vs. BOSTON SCIENTIFIC CORP., 17-cv-00528
SUTLIFF, Amanda vs. BOSTON SCIENTIFIC CORP., 17-cv-00536
TIGNER, Tammy vs. BOSTON SCIENTIFIC CORP., 17-cv-01241
WALLACE, Margaret vs. BOSTON SCIENTIFIC CORP., 17-cv-02450
WELSH, Pamela vs. BOSTON SCIENTIFIC CORP., 17-cv-02568
WILSON, Gwendolyn vs. BOSTON SCIENTIFIC CORP., 17-cv-02106
WITTENBORN, Evelyn vs. BOSTON SCIENTIFIC CORP., 17-cv-02571
ZEITER, Mary vs. BOSTON SCIENTIFIC CORP., 17-CV-01098

BOSTON SCIENTIFIC CORPORATION'S OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF STEPHEN F. BADYLAK, D.V.M., PH.D., M.D.

Defendant Boston Scientific Corporation ("Boston Scientific") submits the following Opposition to Plaintiffs' Motion and Memorandum of Law in Support of Their Motion to Exclude the Opinions and Testimony of Stephen F. Badylak, D.V.M., Ph.D., M.D. ("Mtn. to Exclude Dr. Badylak").[1] Boston Scientific respectfully shows the Court as follows:

INTRODUCTION

Plaintiffs' Motion to Exclude Dr. Badylak is largely premised on partial truths, a misstated record, and outright contradictions. Dr. Badylak is a well-known expert in the field of biomaterials. He is currently employed at the University of Pittsburgh in the McGowan Institute for Regenerative Medicine where he is the Deputy Director of the McGowan Institute and Director of the Center for Preclinical Studies. *See* November 21, 2014 Expert Report of Stephen F. Badylak, D.V.M., Ph.D., M.D., ("Nov. 21, 2014 Dr. Badylak Rep."), at p1.[2] He is a full professor in the Department of Surgery and a full professor in the Department of Bioengineering. *Id.* He has been trained as a veterinarian, a clinical pathologist, an anatomic pathologist, a medical doctor, and a biomaterials scientist. *Id.*

Dr. Badylak has extensive experience evaluating biomaterials used in the human body, including polypropylene mesh. *Id.* He has authored more than 300 peer-reviewed articles and holds more than 50 patents in the field of biomaterials. *Id.* He has also been the principal investigator for more than 250 sponsored research projects. *Id.* at p2. In fact, through a grant from

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1 Plaintiffs filed Motions to Exclude Dr. Badylak in multiple wave cases, but all such motions are identical.

2 A true and accurate copy of the November 21, 2014 Expert Report and accompanying Exhibit B/reliance list of Stephen F. Badylak, D.V.M., Ph.D., M.D. is attached as Exhibit A.

the National Institutes of Health ("NIH"), Dr. Badylak is currently engaged in research investigating polypropylene surgical mesh materials used in female pelvic floor reconstruction. *See* January 14, 2015 Wave Deposition of Dr. Badylak ("Jan. 14, 2015 Badylak Dep."), at 272:21-273:23. Notwithstanding his impeccable qualifications, Plaintiffs move to exclude several of Dr. Badylak's opinions.

This Court has previously ruled on the arguments in Plaintiffs' Motion and the same rulings should apply here, as Dr. Badylak offered the same opinions and Plaintiffs' do not identify any additional bases for excluding his opinions. *Frankum v. Boston Sci. Corp.*, No. 2:12-CV-00904, 2015 WL 1976952, at *35 (S.D.W. Va. May 1, 2015).

In support of their Motion to Exclude Dr. Badylak, Plaintiffs assert the following arguments: (1) Dr. Badylak offers impermissible testimony on Chevron Phillips' state of mind regarding the material safety data sheet ("MSDS"); (2) Dr. Badylak offers unsupported opinions regarding the risk/benefit or safety and efficacy of Boston Scientific's polypropylene mesh devices; (3) Dr. Badylak failed to consider literature that correlates microscopic tissue findings to clinical symptoms; and (4) Dr. Badylak failed to investigate evidence related to oxidative degradation. These arguments fail for several reasons.

First, Plaintiffs' MSDS attack is based on a misconception of Dr. Badylak's MSDS opinions. Boston Scientific concedes that Dr. Badylak will not offer opinions on Chevron Phillips' state of mind. Rather, as a result of his extensive experience evaluating MSDSs, Dr. Badylak offers opinions that relate to the state of biomaterials science and the information known about polypropylene, including information contained in a MSDS for polypropylene. Plaintiffs identify no basis for challenging these opinions, and Dr. Badylak should be allowed to offer testimony regarding the MSDS, consistent with the Court's prior Orders.

Second, Plaintiffs' argument that Dr. Badylak failed to consider relevant literature regarding the risks, benefits, safety, and efficacy of Boston Scientific's polypropylene mesh devices is in direct contradiction to the record, including Dr. Badylak's expert reports, the literature identified on the reliance lists to his expert reports, and Dr. Badylak's own testimony. Indeed, Dr. Badylak has testified that he "certainly did a literature review" and considered "the whole spectrum, the good, the bad, the ugly."

Third, Plaintiffs criticize Dr. Badylak for allegedly failing to consider literature addressing a correlation of pathologic tissue responses seen in explanted mesh to clinical symptoms, but tellingly, they cannot identify a single publication Dr. Badylak failed to consider. Plaintiffs' argument is without foundation and is additionally not the proper subject of a *Daubert* motion.

Lastly, Plaintiffs ask the Court to exclude Dr. Badylak's degradation opinions for failure to test the *theory* proposed by Plaintiffs' expert, Dr. Iakovlev. Not only has this theory failed to gain acceptance in the scientific community, Plaintiffs' argument is again not supported by the record. Dr. Badylak testified that he has evaluated "degradation products" and the "host response to a degradative process"—and that he "absolutely considered degradation as one of the possible contributing factors."

Boston Scientific respectfully moves this Court to deny Plaintiffs' Motion to Exclude Dr. Badylak's Opinions and Testimony. Dr. Badylak is qualified to offer the above opinions, and he has offered a reliable basis for all such opinions. The opinions Dr. Badylak offers in these cases are within his knowledge, skill, experience, training, and education; are based on sufficient facts and data; are derived from reliable scientific principles and methods; and will be helpful to the jury. Fed. R. Evid. 702.

ARGUMENT AND AUTHORITIES

A. Dr. Badylak Offers No Opinions on Chevron Phillips' State of Mind or Intent Related to the MSDS.

To begin, Plaintiffs erroneously state that "Dr. Badylak has previously been precluded by this Court from offering testimony related to the MSDS's medical application caution." Mtn. to Exclude Dr. Badylak at p1. In actuality, this Court has limited Dr. Badylak's testimony on the MSDS only as it relates to "Chevron Phillips' state of mind or intent associated with the MSDS . . . ." *Tyree v. Boston Scientific Corp.*, No. 2:12-cv-08633, 2014 WL 5320566, at *105 (S.D. W. Va. Oct. 17, 2014) (Goodwin, J.) (emphasis added). To be clear, Boston Scientific concedes that Dr. Badylak will not offer testimony on Chevron Phillips' state of mind or intent.

Rather, Dr. Badylak offers the following limited opinions regarding the MSDS:

- "[T]he same raw material source for this polypropylene [HGX-030-01] was used from 1997 forward." Nov. 21, 2014 Dr. Badylak Rep. at p6.
- "Although there was a change in the language of the MSDS in the 2004 timeframe, this language was not associated with any change in the characteristics of the raw material." *Id.*
- "I have not seen any evidence to indicate the additional language was supported by safety concerns or other scientific data." *Id.*
- [Regarding chemical-mediated degradation of the resin] "[T]his comment specifies concentrated sulfuric acid, fuming nitrate acid, and very high temperatures . . . [that] are far different than the environment of the human body." *Id.*

In a footnote, Plaintiffs argue that "Dr. Badylak has offered no evidence in his reports, deposition, or resume that he has any experience creating, reviewing, or analyzing MSDS . . . [and] [t]herefore, he is likewise unqualified to offer opinions related to MSDS." Mtn. to Exclude Dr. Badylak, p3, fn1. Plaintiffs unsuccessfully raised this exact same argument in the consolidated Pinnacle and Obtryx cases—also in a footnote. *See* Plaintiffs' Memorandum of Law in Support of Their Motion to Exclude the Opinions and Testimony of Stephen F. Badylak, D.V.M., Ph.D.,

M.D., Case 2:13-cv-07965, Docket No. 114, at p5, fn1 (July 18, 2014); Case 2:12-cv-08633, Docket No. 213, at p7, fn2 (Aug. 1, 2014). The Court declined to adopt plaintiffs' argument in entirety, but rather limited Dr. Badylak's MSDS testimony only as it relates to Chevron Phillips' state of mind. *See Tyree v. Boston Scientific Corp.*, 2014 WL 5320566, at *105. The Court should likewise reject Plaintiffs' argument here.

The MSDS medical application caution relates to biomaterials generally and the biocompatibility of polypropylene specifically. Dr. Badylak is a medical doctor, pathologist, and biomaterials scientist who has extensive experience evaluating information contained in a MSDS. In fact, Dr. Badylak has testified that he is not only familiar with MSDSs, but that he receives them in his laboratory "[e]very day." *See* January 31, 2014 MDL Deposition of Dr. Badylak ("Jan. 31, 2014 Badylak Dep.") at 312:14-23; *see also id.* at 313:13-16 ("Q. Like we said, you're familiar with these documents in the course of your practice, having a laboratory? A. Yes.").[3] As such, he is qualified to offer opinions related to the MSDS at issue here.

Rule 702(a) permits expert testimony if the expert's "specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a). Expert testimony "is presumed to be helpful unless it concerns matters within the everyday knowledge and experience of a lay juror." *Kopf v. Skyrm*, 993 F.2d 374, 377 (4th Cir. 1993). Because a jury does not possess everyday knowledge or experience with a MSDS, Dr. Badylak's testimony will assist the jury in explaining the significance, or insignificance, of the MSDS. Dr. Badylak's testimony will allow the jury to understand how scientists and physicians use the MSDS and what information they glean from the MSDS.

[3] A true and accurate copy of relevant excerpts from Dr. Badylak's January 31, 2014 MDL Deposition are attached as Exhibit B.

Moreover, Dr. Badylak's MSDS opinions were derived through a reliable methodology that was fully delineated in his expert reports. Indeed, Plaintiffs questioned Dr. Badylak's opinions at deposition, and they identify no basis here for challenging the relevance, reliability, or methodology of Dr. Badylak's actual MSDS opinions.

Plaintiffs' claim that Dr. Badylak "has offered no evidence" and is "likewise unqualified to offer opinions related to the MSDS," Mtn. to Exclude Dr. Badylak at p3, fn1, is without merit. Plaintiffs identify no basis for either position, and the record refutes Plaintiffs' argument in its entirety. Dr. Badylak has provided multiple, reliable bases for his MSDS opinions, and he is qualified to opine on the MSDS, consistent with the Court's prior Orders.

B. Dr. Badylak's Opinions Regarding the Risk/Benefit Analyses and Safety and Efficacy of Boston Scientific's Polypropylene Mesh Devices Have a Reliable Basis and Derive from a Sound Scientific Methodology.

When previously considering Plaintiffs' arguments, this Court denied their motion, stating, "Similarly, the plaintiff's arguments regarding Dr. Badylak's clinical experience are also without merit. Dr. Badylak has extensive experience in the field of biomaterials, including the design of implantable surgical mesh devices." *Frankum v. Boston Sci. Corp.*, 2015 WL 1976952, at *35 (S.D.W. Va. May 1, 2015). Plaintiffs mislead the Court in their request to exclude Dr. Badylak's opinions regarding the risk/benefit analyses and safety and efficacy of Boston Scientific's polypropylene mesh devices. Plaintiffs claim that Dr. Badylak failed to perform a "comprehensive review" of literature specific to Boston Scientific's polypropylene mesh devices. Mtn. to Exclude Dr. Badylak at p8.

However, Plaintiffs conveniently omit reference to Dr. Badylak's testimony where he unequivocally testified that he reviewed and relied upon the relevant medical and scientific literature in forming his opinions, including literature specific to Boston Scientific's pelvic mesh devices. *See* Jan. 31, 2014 Badylak Dep. at 94:24-95:9. When asked whether he performed his

"own research into the field of clinical literature on the issue of polypropylene and tissue response in the human body," Dr. Badylak testified, **"I certainly did a literature review."** *See id.* at 111:5-15. Plaintiffs likewise omit reference to the record where Dr. Badylak testified to the following:

- " . . . I've read literally hundreds of articles now on clinical studies [of polypropylene mesh in humans], results of clinical studies." *Id.* at 120:21-121:5.
- " . . . I requested several things; position statements, whatever we could find in the way of long-term/short-term studies with different products." *Id.* at 122:15-19.
- "Q. And now Exhibit B identified probably at least 200 articles of which some relevance, either clinically or scientifically, to the issues involved in this matter, fair? A. And which helped in forming my opinion, correct." *Id.* at 124:17-22.

Most telling to the unreliability of Plaintiffs' argument—and conversely, the reliability of Dr. Badylak's methodology in reaching his opinions on the risks, benefits, safety, and efficacy of Boston Scientific's polypropylene mesh device—is Dr. Badylak's recent testimony:

> Q. Doctor, as—within your role as an expert witness in this litigation, have you had an opportunity to evaluate the clinical literature specific to the polypropylene devices at issue? A. Yes. Q. And in evaluating that literature, is it fair to say that you have considered both the positive and maybe those studies that had not as positive findings? **A. We looked at all of them, yeah, the whole spectrum, the good, the bad, the ugly, and you make your conclusions based upon your own experience and the preponderance of the literature and the experts in the field.**

See Jan. 14, 2015 Badylak Dep. at 289:13-290:6 (emphasis added).[4]

Exhibit B to Dr. Badylak's expert report further reveals the flaws in Plaintiffs' argument. Exhibit B includes a list of materials Dr. Badylak reviewed and relied upon in forming his opinions.[5] On this list is identification of more than 200 relevant medical and scientific publications, including more than 20 publications that evaluate the risks and benefits and safety

[4] A true and accurate copy of relevant excerpts from Dr. Badylak's Jan. 14, 2015 Deposition are attached as Exhibit C.

[5] Boston Scientific directs the Court to the attached Exhibit A, which includes Dr. Badylak's reliance list (Exhibit B to his Expert Report).

and efficacy of Boston Scientific's polypropylene mesh devices.[6] When Dr. Badylak was recently asked whether he "remember[ed] any specific articles . . . relative to any of the Boston Scientific products," he identified three such articles and informed Plaintiffs' counsel that, "[I]f we go through this entire list, you'll see that there are—**there are references that have evaluated the safety and efficacy of these devices**." *See id.* at 123:22-124:19 (emphasis added).

In *Sanchez v. Boston Scientific Corporation*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W.Va. Sept. 29, 2014), this Court found that plaintiff's expert, Dr. Peggy Pence—a consultant for medical products companies—was qualified to opine on the safety and efficacy of Boston Scientific's polypropylene mesh devices by virtue of her "experience in the research and development of medical devices" and her "accumulated knowledge that is relevant to this case . . . ." *Id.* at *33. The Court further found that Dr. Pence's opinions were reliable, as they were "backed by authoritative studies . . . ." *Id.*

Similarly, Dr. Badylak is qualified to opine on the risks, benefits, safety, and efficacy of Boston Scientific's polypropylene mesh devices by virtue of his extensive experience in the research and development of medical devices, including polypropylene devices, and the vast information he has evaluated relevant to these cases. *See* Nov. 21, 2014 Dr. Badylak Rep. at pp1-2, Exhibit B. Dr. Badylak's opinions are also reliable, as Dr. Badylak has identified multiple,

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[6] *See, e.g.*, Ross, S, et al., "Transobturator Tape Compared With Tension-Free Vaginal Tape for Stress Incontinence," *Am. College Obstet. & Gynecol*, v.114, no6 (2009); Basu, M., et al., "Three-year results from a randomized trial of a retropubic mid-urethral sling versus the Miniarc single incision sling for stress urinary incontinence," *Int. Urogynecol. J* (2013); Renganathan, A., et al., "A series of Advantage suburethral slings," *J of Obstet. & Gynaecol* (2011); Serels, S, et al., "Safety and Efficacy of the Solyx Single-Incision Sling for the Treatment of Stress Urinary Incontinence," *UroToday Int J*, v4 (2011); Jeffrey, S, et al, "High risk of complications with a single incision pelvic floor repair kit: results of a retrospective series," *Int Urogynecol. J* (2013); Shapiro, A, et al., "Short Term Results of Pinnacle Procedure Used to Treat Anterior/Apical Prolapse in 43 Patients," *Female Pelvic Med. & Reconstructive Surgery*, v16, 2o.2 (Suppl), Mar/Apr. 2010; Vu, M, et al., "Minimal mesh repair for apical and anterior prolapse: initial anatomical and subjective outcomes," *Int Urogynecol J* (2012). *See e.g.*, Exhibit A, at pp35-39.

reliable bases for his opinions, including over 200 medical and scientific "authoritative studies," more than 20 of which are specific to Boston Scientific's devices. *See Sanchez*, 2014 WL 4851989, at *33.

The record shows the fallacy in Plaintiffs' assertion that Dr. Badylak has "neither reviewed the applicable scientific and medical literature," Mtn. to Exclude Dr. Badylak at p7. Plaintiffs' statement is simply untrue. Dr. Badylak has clearly reviewed the relevant literature, including that which may be contrary to his opinions. He is likewise more than qualified to opine on the risks, benefits, safety, and efficacy of Boston Scientific's polypropylene devices, and he has provided multiple, reliable bases for these opinions. Accordingly, Plaintiffs' Motion to Exclude Dr. Badylak's Opinions and Testimony should be denied.

C. Dr. Badylak's Opinions Regarding Microscopic Findings of Explanted Polypropylene Mesh and the Lack of Correlation to Clinical Symptoms Have a Reliable Basis.

Plaintiffs again mislead the Court when they claim that "Boston Scientific never disclosed Dr. Badylak for th[e] purpose [of offering opinions related to the inability of a pathologist to correlate microscopic findings to clinical symptoms]." Mtn. to Exclude Dr. Badylak at p10. In addition, this argument is not the proper subject of a *Daubert* challenge, but is better addressed on cross-examination.

Dr. Badylak issued case-specific supplemental reports in Wave cases where he received and examined explanted mesh and/or tissue specimens from Plaintiffs.[7] In these reports, Dr. Badylak stated, "The presence of occasional nerves, blood vessels and skeletal muscle does not correlate to any clinical finding of pain or other purported adverse event." *See, e.g.*,

[7] At the time Plaintiffs filed this Motion, Dr. Badylak had executed 32 such reports. Upon receipt of additional pathology from Plaintiffs, Dr. Badylak subsequently executed two additional case-specific reports in the matters of *Linda Howard v. Boston Scientific Corporation* and *Bertha Jimenez v. Boston Scientific Corporation*.

Dr. Badylak's Supplemental Report for Plaintiff Bambi Teague.[8] For Plaintiffs to suggest that Dr. Badylak did not disclose these opinions is another misstatement of the record.

Plaintiffs next claim that Dr. Badylak ignored "scientific and medical literature correlating microscopic findings with physical symptomatology . . . ." Mtn. to Exclude Dr. Badylak at p10. In support of their argument, Plaintiffs cite Dr. Badylak's testimony where he explained the association of pain in the context of burn victims, dentistry, hernias, osteoarthritis, esophagitis, and post-hysterectomy pain. Notwithstanding the stark differences in etiology of pain seen in these other contexts, notably absent from Plaintiffs' argument is identification of any literature Dr. Badylak allegedly failed to consider that addresses a correlation of pain symptoms from microscopic tissue responses seen in explanted mesh specimens.

Plaintiffs critique Dr. Badylak for failing to "cite[] or rel[y] upon any of this body of literature," *id.*, yet they cannot even provide the Court a single example of what literature he allegedly failed to consider. As such, Plaintiffs' argument is without foundation and should be denied.

In regard to its "gatekeeper" role, this Court has stated that it "'need not determine that the proffered expert testimony is irrefutable or certainly correct' . . . [a]s with all other admissible evidence, expert testimony is subject to testing by 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *Tyree v. Boston Scientific Corp.*, 2014 WL 5320566, at *3 (citing *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998) (noting that "[a]ll *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful")). Plaintiffs have identified no basis for exclusion of Dr. Badylak's opinions regarding correlation (or lack thereof)

[8] A true and accurate copy of Dr. Badylak's Supplemental Report for Plaintiff Bambi Teague is attached as Exhibit D.

of microscopic tissue findings to clinical symptoms. Plaintiffs' disagreement with Dr. Badylak's opinions is not appropriate for a *Daubert* motion, but is better reserved for "vigorous cross-examination." *See id.*

D. Dr. Badylak's Opinions on Oxidative Degradation are the Product of a Reliable Scientific Methodology.

This Court previously denied Plaintiffs' motion based on the same arguments made here, "Upon review of the deposition, I do not find Dr. Badylak's testimony sufficiently contradictory to undermine the reliability of his expert opinions. Accordingly, the plaintiff's motion with regard to degradation is DENIED." *Frankum* 2015 WL 1976952, at *36. For the reasons re-stated below, the Motion should again be denied.

Although not readily apparent on the face of their Motion, it appears that the crux of Plaintiffs' argument is that Dr. Badylak should be precluded from testifying about oxidative degradation because he did not test the polarized light "degradation bark" theory proposed by Plaintiffs' expert, Dr. Iakovlev—a theory that has not been tested, let alone accepted, by any clinician or scientist who is not a Plaintiff's expert in this litigation. *See* Jan. 14, 2015 Badylak Dep. at 286:2-25, 288:3-16, 289:7-12. Not only is this argument illogical, it is not appropriate for a *Daubert* motion, but is more appropriately addressed on cross examination.

Plaintiffs tell the Court that Dr. Badylak (1) "did not even explore ways to confirm or disprove the Iakovlev findings [of polypropylene degradation]" or (2) "rule out degradation as occurring in any of the women in these cases." Mtn. to Exclude Dr. Badylak at pp12-13.

In direct contradiction to these assertions, Dr. Badylak has, in fact, evaluated and considered purported polypropylene degradation in reaching his opinions. Specifically, Dr. Badylak testified that he has evaluated "degradation products" and the "host response to a

degradative process"—and not seen evidence of either phenomenon. *See* Jan. 31, 2014 Badylak Dep. at 269:22-270:12.

Dr. Badylak has also reviewed and relied upon the peer-reviewed, published work of other scientists such as Dr. Clave and Dr. Woodruff who evaluated and tested the theory of oxidative degradation using well-accepted scientific methodologies. *See* Jan. 14, 2015 Badylak Dep. at 288:3-289:6, 292:6-293:16.

Lastly, Dr. Badylak testified that he "**absolutely considered degradation as one of the possible contributing factors,**" explaining that **"[y]ou never want to not look at all the information or consider all the possible reasons."** *Id.* at 290:21-291:5 (emphasis added). For Plaintiffs to suggest that Dr. Badylak's degradation opinions are "nothing more than the result of willful blindness," Mtn. to Exclude Dr. Badylak at p11, is disingenuous at best.

The Court should permit Dr. Badylak to offer testimony related to claims of oxidative degradation. To the extent that Plaintiffs have qualms about Dr. Badylak's oxidative degradation opinions, they are more appropriately raised on cross-examination.

CONCLUSION

For all of the foregoing reasons, the Court should deny Plaintiffs' Motion to Exclude the Opinions and Testimony of Dr. Stephen F. Badylak in its entirety. The opinions Dr. Badylak offers in these cases are in harmony with the Court's prior Orders; are within the scope of his expertise; and are the product of a reliable scientific methodology.

Dated: February 1, 2018

Respectfully Submitted

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CERTIFICATE OF SERVICE

I hereby certify that on February 1, 2018, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this matter.

/s/Eric M. Anielak
Eric M. Anielak

COUNSEL FOR DEFENDANT BOSTON SCIENTIFIC CORPORATION